IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANTS	:	SCHREINER
SERIAL NO.	:	**09/701,710**
FILED	:	1 December 2000
FOR	:	COSMETIC OR DERMATOLOGIC PREPARATIONS CONTAINING CATECHINS OR GREEN TEA EXTRACT
ART UNIT	:	**1619**
EXAMINER	:	**Lauren Q. Wells**

18 August 2003

Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF ON APPEAL PURSUANT TO 37 CFR § 1.192

SIR:

This is an appeal from the final rejection of claims 5-12 and 27-31, which are the only claims pending in the application.

(1) REAL PARTY IN INTEREST

The real party in interest is **Beiersdorf AG** by virtue of an assignment recorded on at Reel 011423, Frame 0071.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals and interferences.

(3) STATUS OF CLAIMS

Claim 5-12 and 27-31 stand rejected.

(4) STATUS OF AMENDMENTS

There are no other unentered amendments.

(5) SUMMARY OF INVENTION

The present invention relates to a method selected from the group consisting of treatment and/or care of dry skin; increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid

synthesis; strengthening the lipid barrier of the human skin and combinations thereof for a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of a composition comprising of 0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof, based on the total weight of the composition.

Support for this invention can be found on page 5, line 19 through page 6, lines 15 (narrower embodiments of the invention and the corresponding claimed subject matter can be found throughout the specification).

(6) ISSUES

The lone issue is that the appellants assert that claims 5-12 and 27-31 were improperly rejected by the Examiner as being anticipated by Znaiden et al. (U.S. Patent 5,523,090).

(7) GROUPING OF CLAIMS

Claims 5-12 include the entire scope of treatment methods and these claims stand and fall together.

Claims 27-31 are each directed toward a specific method of treatment and as such can be treated separately on the merits.

(8) ARGUMENTS

35 U.S.C. 103(a) rejection - Claims 5-12 and 27-31 are not anticipated by Znaiden et al.

A. Prosecution History (Znaiden is a recycled rejection which had previously been considered and withdrawn by Examiner Berman)

Before presenting arguments against the merits of the Znaiden rejection, the appellants wish to bring to the Board's attention the prosecution history of this application which has some singular features which appear to run counter to the PTO's goal of compact prosecution:

(1) A rejection based on the Znaiden reference was first made by Examiner Berman in the Office Action dated 20 December 2001 (Paper No. 6).

(2) The appellants responded to this rejection in the amendment under 37 CFR §

1.111 dated 8 March 2002 whereupon Examiner Berman rescinded the Znaiden rejection in favor of a rejection based on different prior art (this rejection was made prematurely final and had to be petitioned to correct the status of the application - see Petition Decision from John Doll, Group Director Tech. Center 1600, dated 3 January 2003)

(3) The appellants responded to the Office Action of 9 October 2002 (Paper No. 11) which resulted in the rescinding of the rejection based on the different prior art. However, the Office Action (a final rejection) by Examiner Wells (different examiner) reinserted the rejection over the Znaiden reference.

(4) The appellants object to this rejection on two grounds:

(a) If the Znaiden rejection by Examiner Wells represents a different type of rationale than that previously proffered by Examiner Berman, then this constituted a new grounds of rejection and the Office Action of 18 March 2003 was again made prematurely final (In the interest of compact prosecution, the appellants elected not to petition again the Group Director to withdraw this holding of premature finality).

(b) If the Znaiden rejection by Examiner Wells was intended to be substantially the same as Examiner Berman's rejection, it is unclear why the appellants should now be forced to revisit an old issue that had previously been decided especially when MPEP 706.04 (Previous Action by Different Examiner) explicitly states that full faith and credit should be given to the previous examiner.

B. Standards of Review for Anticipation Rejection

(1) Each and every element is expressly or inherently described

MPEP 2131 states that "'A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628,

631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).".

(2) Described element(s) is/are in as complete a detail as in the claim

MPEP 2131 also states that "'The identical invention must be shown in as complete detail as is contained in the...claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d, 1913, 1920 (Fed. Cir. 1989)."

Moreover, it has further been held that "Rejection for anticipation requires, as first step in inquiry, that all elements of claimed invention be described in single reference, and such reference must describe applicant's claimed invention sufficiently to have placed person of ordinary skill in possession of it." see *In re Spada*, 15 USPQ2d 1655, (Fed. Cir. 1990) and that the reference "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without ***any*** need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." see *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972).

(3) Examiner Must Provide Rationale for Inherency

The Examiner's comments in the Advisory Action (Paper No. 17) appear to indicate that at least part of the basis for the rejection lies with a holding of inherency.

MPEP 2112 (Requirements of Rejection Based on Inherency; Burden of Proof) states "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).....To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed.

Cir. 1999), see also *Mentor H/S, Inc. v. Medical Device Alliance, Inc. (Mentor II)*, 244 F.3d 1365, 58 USPQ2d 1321 (Fed. Cir. 2001) and *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

C. Statement of Facts About Znaiden Reference

(1) The Znaiden reference primarily describes compositions wherein "certain acids" (e.g. alpha hydroxyl acids or an inositol phosphoric acid), solubilize a xanthine when the ratio of xanthine to the acid is in a "specific range according to the invention" (e.g. about 1:1000 to about 4:1) - see col. 3, lines 24-39.

(2) Znaiden's compositions are used to improve skin strength and firmness and reducing signs of cellulite (see e.g. Abstract, col. 2, lines 61-64 and col. 8, lines 49-53) not the applicants' claimed method of use.

(3) There is no indication that the green tea extracts used in Examples 10-12 of Znaiden actually includes "catechins, a gallic ester of a catechin, or mixtures thereof" as is required by the appellants' claims.

(4) Example 12 was used as part of cellulite treatment composition and there is no indication that the epicatechin used in Example 12 was intended for use as anything other than as an anti-inflammatory.

D. Examiner's Rejection Does Not Meet the Requirements/Standard of Review for Anticipation

(1) Each and every element is NOT expressly described

As stated above, there is no indication that compositions of Examples 10-11 described by Znaiden actually contains catechins, a gallic ester of a catechin, or mixtures thereof. Even if these examples contained these elements (Example 12 does recite use of epicatechin), there is no indication that this element was added for anything other than their recited use as an anti-inflammatory (see col. 6, lines 6-11).

Moreover, there is no indication that even when considering Example 12 (directed toward a cellulite treatment composition), Znaiden expressly described a method for treatment and/or care of dry skin; increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof for a human in need thereof.

(2) Described elements are NOT in as complete a detail as in the claim

It is clear from reading the Znaiden reference that the main thrust of their disclosure is the inventive use of a combination of alpha hydroxyl acids or an inositol phosphoric acid to solubilize a xanthine when the ratio of xanthine to the acid is in a "specific range according to the invention". Even if could be affirmatively established that catechins, a gallic ester of a catechin, or mixtures thereof are part of Znaiden's invention beyond their use in cellulite treatment compositions, there is no indication that these elements were used for any other purpose beyond their art recognized properties and were intended for use as claimed by the appellants.

As such, even if it could be argued that each and every element is expressly or inherently present within the teachings of Znaiden, the disclosure of these elements would not place one of ordinary skill in the art "in possession" of the appellants' claimed invention nor could one of ordinary skill in the art avoid the improper "pick and choose" standard for establishing an anticipation rejection.

At best, the Znaiden reference offers an invitation to experiments with no assurances that the artisan would ever arrive at the appellants' claimed invention.

(3) Examiner DID NOT Provide Rationale for Inherency

There is no indication that the green tea extracts of Znaiden actually contain the catechins, a gallic ester of a catechin, or mixtures thereof which are a required element of the appellants' claims. In fact, based on the teachings of Znaiden, there may be reason to believe that this element is not present in their extracts.

Znaiden discloses the enhanced solubility of ***xanthine*** which is a critical element of their invention and in the instances where the green tea extracts were used, the content of these extracts was 86% theophylline (1,3-dimethyl***xanthine***) by weight (see asterisk at the end of Examples 10 and 11)

The lone example where a catechin is used by Znaiden (Example 12 - epicatechin) is directed toward the treatment of cellulite not the appellants' claimed method of use and there is no evidence that epicatechin actually had any effect of the treatment of cellulite, i.e. it was merely added as an additional ingredient to provide an anti-inflammatory effect.

The Examiner recited *In re Papesch* in her Advisory Action (Paper No. 17). However, reliance on this decision is misplaced as the claims are directed toward a method of use not the compounds themselves and it had heretofore been unrecognized that catechins, a gallic ester of a catechin, or mixtures thereof had the properties currently being claimed by the appellants.

Given that Znaiden recognizes the inclusion of catechins and derivatives thereof as anti-inflammatories, there has been no extrinsic evidence offered by the examiner or technical explanation as to why one of ordinary skill in the art would inherently believe the inclusion of epicatechin in a cellulite treatment composition would produce the appellants' claimed methods especially when viewed in light of the fact that the primary effects on the skin attributed to the invention of Znaiden are directed toward unrelated elements (i.e. "certain acids" and xanthine). Given the lack of supporting evidence, it cannot even be asserted that there is a "possibility" that Znaiden teaches the appellants' invention much less that there is a "probability" or the appellants' claimed methods "would be so recognized by persons of ordinary skill."

(9) CONCLUSION

For the reasons given above, Appellants respectfully request the Board reverse the Examiner's rejection of claims 5-12 and 27-31.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Appellants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess to our Deposit Account No. 14-1263.

Respectfully submitted,
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as an Express mail in an envelope addressed to: Hon. Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22312-1450 on the date indicated below:

Date: **18 August 2003**

By Agata Glinska
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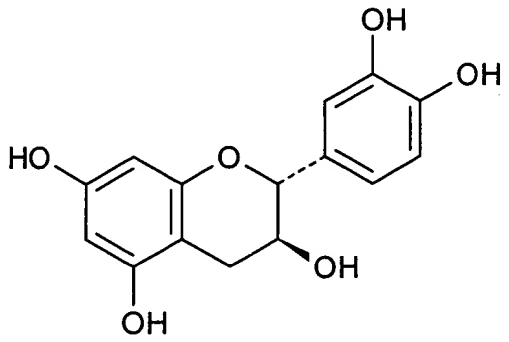
(10) APPENDIX - CLAIMS ON APPEAL

5. A method selected from the group consisting of treatment and/or care of dry skin; increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof for a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of a composition comprising of 0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof, based on the total weight of the composition.

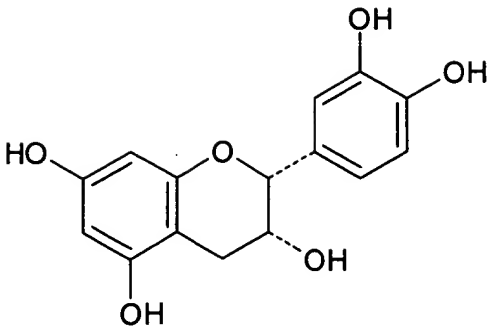
6. The method of Claim 5, wherein the catechin or gallic ester of a catechin are selected from the group consisting of (-)-catechin, (+)-catechin, (-)-catechin gallate, (-)-gallocatechin gallate, (+)-epicatechin, (-)-epicatechin, (-)-epicatechin gallate, (-)-epigallocatechin, and (-)-epigallocatechin gallate.

7. The method of Claim 5, wherein the catechin is



or a gallic ester thereof.

8. The method of Claim 5, wherein the catechin is



or a gallic ester thereof.

9. The method of Claim 5, wherein the catechin or gallic ester of a catechin is obtained from a plant.

10. The method of Claim 9, wherein the catechin or gallic ester of a catechin is obtained from a plant from the *Theaceae* plant family.

11. The method of Claim 9, wherein the catechin or gallic ester of a catechin is obtained from the plant species *Camellia sinensis*.

12. A method selected from the group consisiting of treatment and/or care of dry skin; increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof for a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of an extract from a plant or plant parts which comprises a catechin, a gallic ester of a catechin, or mixtures thereof.

27. The method of any one of claims 5-12 wherein the method is treatment and/or care of dry skin.

28. The method of any one of claims 5-12 wherein the method is increasing the synthesis rate of ceramides in human skin.

29. The method of claim 28 wherein the ceramides are ceramides 1, 2 and 3.

30. The method of any one of claims 5-12 wherein the method is stimulating sphingolipid synthesis.

31. The method of any one of claims 5-12 wherein the method is strengthening the lipid barrier of the human skin.